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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,589	Applicant(s) CARTER ET AL.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2008 has been entered. Claims 1-23 and 33-36 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24, 25, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hilaire et al. (U.S. Publication No. 2005/0085845 A1)** in view of

Colgan et al. (U.S. Publication No. 2003/0040789 A1). Hilaire discloses a method of placing first and second stents into a bifurcation using a stent delivery device (see entire document) comprising the steps of providing a first introducer (102) having a first distal portion (130) with a first distal outer diameter and a first stent (170) and a first proximal portion (110) having a first proximal outer diameter that is less than the first distal outer diameter (for example, see Figure 5), providing a second introducer (104) having a second distal portion (132) with a second distal outer diameter and a second stent (178) and a second proximal portion (112) having a second proximal outer diameter that is less than the second distal diameter (for example, see Figure 5), placing the first and second introducers in a staggered adjacent configuration, wherein the first proximal portion is adjacent to the second distal portion such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter (for example, see Figure 5), placing a first (140) and second (142) wire guide in an adjacent configuration into a main lumen and first and second branch lumens, the second wire guide and introducer advanceable independent of the first introducer (when linking device 160 is released; for example, see the last sentence of paragraph 82), advancing the first and second introducers over the first and second wire guides such that the first distal portion of the first introducer is distal to the second distal portion of the second introducer (for example, see Figure 11) and further such that the first and second introducers are positioned within the main lumen and the first and second branch lumens (for example, see Figure 12). The wire guides disclosed

lead and guide the introducers. Therefore, it is inherent the wire guides enter the lumens before the introducers.

Hilaire fails to disclose the step of placing the staggered, adjacent, introducers (for example, see Figure 5) in a working channel of an endoscope. Colgan discloses a method of deploying a stent (see entire document). Colgan teaches the step of placing an introducer retaining a stent in a working channel of an endoscope (70; for example, see paragraphs 87 and 91). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place Hilaire's introducers in a working channel of an endoscope as taught by Colgan. Doing so would enable the operator to locate stent placement through direct vision (for example, see paragraph 87).

With further respect to claim 28, Hilaire teaches the method described above may be modified such that the first and second stents are deployed simultaneously (for example, see paragraph 94). It would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the stents simultaneously. Doing so would reduce the number of steps to complete the procedure, thus facilitating the procedure.

With further respect to claim 37, Hilaire further discloses the distal ends of the introducers comprise first and second stents (170 and 178), wherein the stents are placed in the main lumen and branch lumens subsequent to placing the wire guides in the lumens (for example, see Figures 10-12).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vardi et al. (U.S. Publication No. 2001/0003161 A1)** in view of **Colgan et al.**

Vardi discloses a method of placing first and second stents into a bifurcation using a stent delivery device (see entire document) comprising the steps of providing a first introducer (12) having a first distal portion (11) with a first distal outer diameter and a first stent (25) and a first proximal portion (elongated portion) having a first proximal outer diameter that is less than the first distal outer diameter (for example, see Figure 2), providing a second introducer (20) having a second distal portion (13) with a second distal outer diameter and a second stent (40) and a second proximal portion (elongated portion) having a second proximal outer diameter that is less than the second distal diameter (for example, see Figure 2), placing the first and second introducers in a staggered adjacent configuration, wherein the first proximal portion is adjacent to the second distal portion such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter (for example, see Figure 2), placing a first (21) and second (31) wire guide in an adjacent configuration external to and independent of the stents into a main lumen and first and second branch lumens (for example, see Figure 5; the distal tips of the wire guides are external to the stents), advancing the first and second introducers over the first and second wire guides such that the first introducer is positioned within the main lumen and first branch lumen and the second introducer is positioned within the main lumen and the second branch lumen (in that the main lumen branches to either the left or straight, thus the straight portion at the branching section is considered a first branch

and the left portion is considered a second branch as claimed; for example, see Figure 6), and deploying the first stent within the first branch lumen and the main lumen (for example, see Figure 6).

Vardi fails to disclose the step of placing the staggered, adjacent, introducers (for example, see Figure 2) in a working channel of an endoscope. Colgan discloses a method of deploying a stent (see entire document). Colgan teaches the step of placing an introducer retaining a stent in a working channel of an endoscope (70; for example, see paragraphs 87 and 91). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place Vardi's introducers in a working channel of an endoscope as taught by Colgan. Doing so would enable the operator to locate stent placement through direct vision (for example, see paragraph 87).

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vardi et al.** in view of **Colgan et al.** and **Shaknovich (U.S. Patent No. 5,669,924)**.

Vardi in view of Colgan discloses the claimed invention (see rejection above for a description of the same limitations recited in claim 30) except for the step of simultaneously deploying the first and second stents within the bifurcation such that at least at least a portion of the first stent is in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen.

Shaknovich discloses a method of placing first (6b) and second (6a) stents in a bifurcation (for example, see Figure 9). Shaknovich teaches the step of simultaneously deploying the first and second stents within the bifurcation such that at least at least a

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portion of the first stent is in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen (for example, see column 8, lines 17-22). It is well within the general knowledge of one having ordinary skill in the art to combine prior art elements to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the step of simultaneously deploying the first and second stents within the bifurcation such that at least a portion of the first stent is in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen in Vardi's in view of Colgan's method as taught by Shaknovich, utilizing Shaknovich's stents. Doing so would reduce the number of steps to complete the procedure, in turn facilitating the procedure. With further respect to claim 31, access to the second branch remains open as the first stent is positioned within the first branch lumen and main lumen in that the second stent is positioned within the second branch and main lumen prior to deployment of both stents (i.e., the stents are expanded simultaneously, and open access is provided around the deflated balloons).

Response to Arguments

Applicant's arguments, see line 30 of page 9 through line 15 of page 10, filed 15 September 2008, with respect to Shaknovich and amended claims 24, 26, and 30 have been fully considered and are persuasive. The rejection of claims 24-32 and 37 over Shaknovich has been withdrawn and new rejection has been set forth above.

Applicant's arguments with respect to Hilaire et al. and amended claims 26-32 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 15 September 2008 regarding Hilaire et al. and amended claim 24 have been fully considered but they are not persuasive. The applicant argues primarily that Hilaire discloses that since the introducers are connected by a releasable linking device and the second wire guide is inserted through the stent of the first wire guide, Hilaire teaches away from advancing the second wire guide and second introducer independent of the first introducer as now claimed in amended claim 24. However, amended claim 24 simply recites "the second wire guide and the second introducer advanceable independent of the first introducer." It is the examiner's position that the second wire guide and the second introducer are advanceable independent of the first introducer when the linking device is released. Furthermore, Hilaire discloses the introducers may be maneuvered separately when desired (for example, see last sentence of paragraph 82). Therefore, Hilaire does not teach away from advancing the wire guides and introducers independently as argued.

Regarding the applicant's argument that Colgan fails to teach or suggest placing first and second introducers in a staggered, adjacent, configuration, it is the examiner's position that Hilaire discloses such a step. Colgan teaches the step of placing an introducer in the working channel of an endoscope to deploy a stent provides the advantage of direct visualization during stent deployment. Therefore, it is the examiner's position that to insert Hilaire's configuration into a working channel of an endoscope as taught by Colgan would have been obvious to one having ordinary skill in the art (see rejection above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
November 17, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773